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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/626,374 | 07/24/2003 | Ernest J. Lee | 01038/2/US | 1215 |
| 26648 | 7590 | 06/21/2004 | EXAMINER | |
| PHARMACIA CORPORATION GLOBAL PATENT DEPARTMENT POST OFFICE BOX 1027 ST. LOUIS, MO 63006 | | | MICHENER, JENNIFER KOLB | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1762 | |

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/626,374

Applicant(s)

LEE ET AL.

Examiner

Jennifer K. Michener

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/15/2003
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, drawn to a method of coating, classified in class 427, subclass 2.14.
- II. Claim 16, drawn to a coated product, classified in class 424.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as application with a single coat.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Karen King on 6/10/04 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-15. Affirmation of this election must be made by applicant in replying to this Office action. Claim 16 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

8. The disclosure is objected to because of the following informalities:
The use of the trademarks Surelease and Opadry, etc. has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 6 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of Trademarks renders the claims indefinite because it does not indicate whether the same material made under a different Trademarked product is equally operational. Moreover, the value of the Trademark is lost to the extent that it becomes descriptive of a product rather than the identification of a source or an origin of a product.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-7, 10-11, 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghebre-Sellassie et al. (4,600,645)

Ghebre-Sellassie teaches coating a solid dosage having an active agent (col. 2, line 37) dispersed therein with a first coating solution of ethylcellulose, a water-insoluble polymer, and a material which modifies the release of the active agent through the coating, acting as Applicant's pore former (col. 3, lines 1-15). The first coating is then

cured (col. 4, lines 10-15). Then Ghebre-Sellassie coats the solid dosage form with a second coating, which may contain the same ethyl cellulose polymer and pore-forming material outlined for the first coating (col. 3, lines 51-53).

While Ghebre-Sellassie fails to specifically teach that the pore former is "water-soluble", Examiner notes that Ghebre-Sellassie teaches that the coating solutions may contain water soluble and/or water dispersible ingredients (col. 2, line 67). It is Examiner's position that one of ordinary skill in the art would have selected the pore former to be one of either water soluble or water dispersible as outlined by Ghebre-Sellassie.

Furthermore, because pore formers allow a slow and sustained release of active agent through pores formed in the non-soluble ethyl cellulose layer, it would have been obvious to one of ordinary skill in the art to select a water-soluble pore former to allow the gastric juices to dissolve the pore forming agents for release of the active agent through the holes created by their dissolution.

Regarding claims 2, Ghebre-Sellassie fails to teach the weight gain associated with the coating step of the first coating, however, it is Examiner's position that selection of a weight gain would have been obvious to one of ordinary skill in the art based on the active agent release profile desired.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claims 3-5, the curing step for the first layer is for 15-60 minutes at a temperature of 45-70 °C, overlapping the ranges claimed by Applicant.

Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Ghebre-Sellassie range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974). These times and temperatures are inherently suitable to cure the coating above the glass transition temperature because Ghebre-Sellassie teaches the same ranges used for the same ethylcellulose coating as Applicant.

Regarding claims 6-7, Ghebre-Sellassie teaches the use of ethylcellulose as the water-insoluble polymer, as outlined above.

Ghebre-Sellassie teaches coating a capsule or pellet, which qualifies also as a tablet, as required by claims 10-11.

Ghebre-Sellassie teaches curing again after application of the second coating (col. 4, lines 23-30), as required by claim 13. This combined two-step curing process taught by Ghebre-Sellassie achieves a significant reduction in curing time compared to the one-step curing method.

The pore former is inherently present in an amount that promotes the extended release of the active agent, as required by claim 14, as is also taught by the reference and outlined above.

Regarding claim 15, it appears that the pore former quantity falls within the range claimed by Applicant (col. 3, lines 20-25). Additionally, Examiner notes that selection of a quantity of pore former would have been selected by an ordinary artisan as a cause-effective variable (determination of which is outlined above) based on the desired release profile of the active agent through the pores created by the dissolution of the pore former.

15. Claims 8-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghebre-Sellassie in view of Heimlich et al. (2003/0129236).

Ghebre-Sellassie teaches that which is disclosed above including the use of ethylcellulose as an ingredient in both of his drug-dosage coating layers and the use of pore formers in these layers. While Ghebre-Sellassie teaches the use of hydroxypropylmethyl cellulose (HPMC) as an ingredient in his second coating, where it would inherently act as a pore former, he fails to teach the use of HPMC in his first coating as such.

Heimlich teaches the use of HPMC as a pore former useful in combination with ethylcellulose to coat solid dosage forms (P39).

Since Ghebre-Sellassie teaches the use of a pore former when coating solid dosage forms with ethylcellulose and Heimlich teaches the use of HPMC as such, Heimlich would have suggested the use of HPMC as the pore former in Ghebre-Sellassie. It would have been obvious to one of ordinary skill in the art to use the teachings of Heimlich in the method of Ghebre-Sellassie to provide Ghebre-Sellassie with an alternative to clays and the like for use as pore formers when coating drug dosage units with ethylcellulose.

While Ghebre-Sellassie teaches the use of a solid dosage unit containing an active drug agent, he fails to specifically teach the drug required by Applicant.

Heimlich teaches the use of clindamycin in the solid dosage form in a method of coating said solid dosage form with ethylcellulose.

Since Ghebre-Sellassie and Heimlich teach coating solid dosages forms with ethylcellulose and Heimlich teaches that clindamycin is suitable as the drug in such dosage forms, Heimlich would have reasonably suggested as obvious to one of ordinary skill in the art the use of clindamycin in the method of Ghebre-Sellassie.

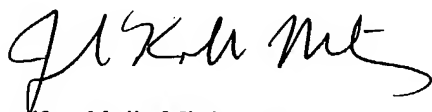
Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Speronello et al. teach that the clay of Ghebre-Sellassie acts as a pore former.

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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6/16/2004